K120820

Rev B
Revised May 2012

510(k) Summary

JUN - 8 2012

Giraffe Blue Spot PT Lite

Submitter Information:

Lumitex, Inc.
8443 Dow Circle
Strongsville, OH 44136
Phone: 440-243-8401
Fax: 440-243-8402
Contact Person: David G. Felty P.E., Director of Engineering
Email: dfelty@lumitex.com
Date Prepared: March 14, 2012

Device Names:

Classification Name: Neonatal Phototherapy Unit
Common Name: Phototherapy Light, Spot PT
Trade Name: Giraffe Blue Spot PT Lite
Product Code: LBI
Classification Number: 21 CFR 880.5700
Class Type: (Class II)

Indications for Use:

The Giraffe Blue Spot PT Lite phototherapy system provides light therapy for the treatment of hyperbilirubinemia, commonly known as neonatal jaundice, during the newborn period in the hospital.

Predicate Device Information:

The Giraffe Blue Spot Phototherapy Lite is substantially equivalent to the following legally marketed product:

Ohmeda Medical Giraffe Spot PT Lite Phototherapy System (K011549)

Substantial Equivalence Comparison:

The following matrix provides a comparison of the basic key equivalence metrics between the Giraffe Blue Spot PT Lite and its predicates. A more extensive table is provided in the Substantial Equivalence section.

Substantial Equivalence Comparison		
	Giraffe Blue Spot Lite Phototherapy System	**Giraffe Spot PT Lite Phototherapy System (Predicate)**
510k Number	TBD	K011549
Light Delivery System	Single Fiber Optic Cable	Single Fiber Optic Cable with a quartz rod buffer between the fiber and the light source
Wavelength	Light output is limited to blue light, typically within 400nm – 500nm.	Light output is white light from a metal halide bulb allowing for a very broad spectrum, typically between 350nm – 700nm.
Bulb Life	7,000 Hours	2,500 Hours
Peak Wavelength	450nm – 475nm	570nm – 590nm (typical peak)
Light Intensity[1]	At a distance of 38 cm there is a treatment area of 990 cm^2 and a spectral irradiance of 45 $\mu W \cdot cm^{-2} \cdot nm^{-1}$ +25%/-20%.	At a distance of 38 cm there is a treatment area of 315 cm^2 and a spectral irradiance of 57.6 $\mu W \cdot cm^{-2} \cdot nm^{-1}$ ±25%.
Light Output Adjustment	Light output may be adjusted by changing the distance from the lens of the device to the patient. As the lens is moved farther from the patient the light output per area decreases and the area increases.	Light output may be adjusted by changing the distance from the lens of the device to the patient. As the lens is moved farther from the patient the light output per area decreases and the area increases.
Light Source Type	Single Light Emitting Diode	Single Metal Halide Bulb

[1] American Academy of Pediatrics, clinical practice guideline, subcommittee on hyperbilirubinemia: Management of hyperbilirubinemia in the newborn infant 35 or more weeks of gestation, 2004; 297-316 recommends spectral irradiance greater than 30.0 $\mu W \cdot cm^{-2} \cdot nm^{-1}$ for effective therapy treatment.

Product Description:

The Giraffe Blue Spot PT consists of two main sub-assemblies the same as the predicate devices; a sub-assembly that generates the phototherapy light and a sub-assembly that transfers the

light to the patient. For the Giraffe Blue Spot PT Lite the two halves are generically known as the Light Pipe and the Light Box.

The Light Pipe is a flexible arm that consists of a single optical fiber passing through a set of springs to a shade assembly that will focus the output light to the desired spot size from a given distance. The spring portion of the assembly provides the ability to quickly position the light pipe without the need for tools, while also providing sufficient rigidity to keep light pipe from drooping or rising out of position.

The phototherapy light provided to the patient is controlled by the operator by adjusting the positioning of the output shade above the patient. The therapy delivered to the patient varies directly with the distance of the light shade from the patient being treated. The operator changes the intensity and spot size by manually adjusting this distance.

The Light Box contains a single blue light LED providing the phototherapy light source that is then transmitted utilizing the Light Pipe. The Light Pipe is used to position and direct the therapy light onto the patient from above. There is no direct contact with the patient. The light source operates at a single light intensity and is not adjustable by the operator or patient.

The phototherapy LED emits light in a narrow bandwidth; 400nm – 500nm with a 450nm – 475nm peak. As such, and confirmed by physical testing to IEC60601-2-50, there are very low levels of energy in the ultraviolet (UV) or infrared (IR) regions of the light spectrum.

The Light Box also contains an internal cooling fan to cool the internal circuitry and the phototherapy LED in order to extend product lifetime. The device is ready for use once connected to an AC power source. The device is equipped with an internal switching power supply that accepts 100-240VAC 50/60Hz power. Power connection is made through supplied power cord connected to an IEC appliance inlet with built-in fuses protection.

The front cover of the unit provides numerous operating features including an ON/OFF pushbutton to turn the phototherapy LED on and off, LED indicators for Standby/Ready, phototherapy ON and over/under temperature; and an hour meter that tracks accumulated phototherapy hours on the device. The over/under temperature indicator provides feedback to the operator that the phototherapy LED is currently too hot, or too cold, to allow it to be turned on and that the fan is actively cooling, or warming, the unit until appropriate temperatures are reached. Once the unit is at the appropriate temperature range, the Standby/Ready indicator illuminates.

On the bottom of the unit are the IEC power inlet and associated fuses, a potential equalization ground stud and the air intake filter. A mounting bracket on the back of the unit allows the unit

to be positioned and secured in the dovetail slot of an accessory rail. Tightening three socket head mounting screws holds the unit in position.

LEDs have very little degradation over their lifetime with proper use and care. During normal operating conditions the device is expected to last for over 7,000 hours and provide the minimum levels of therapy as defined by the "American Academy of Pediatrics, clinical practice guideline, subcommittee on hyperbilirubinemia: Management of hyperbilirubinemia in the newborn infant 35 or more weeks of gestation, 2004; 297-316".

Performance Data:

Since the treatment of neonatal hyperbilirubinemia with phototherapy is a well-established clinical practice, clinical or animal testing to demonstrate safety and effectiveness is not necessary. The product has been designed following Lumitex design controls as required by 21 CFR 820, Subpart C and subjected to extensive 3rd party agency approvals and in-house bench testing.

Testing:

The Giraffe Blue Spot PT Lite is currently undergoing extensive 3rd party testing to numerous global standards.

Intertek ETL has certified the product to numerous standards. This effort includes, but is not limited to, the following:

Standards	Title
IEC 60601-1 Issued:1988/12/01 Ed:2	Medical Electrical Equipment Part 1: General Requirements for Safety; (Amd. 1-1991) (CENELEC EN 60601-1: 1990) (Amd. 2-1995) (Corrigendum-1995)
IEC 60601-1-2 Issued:2007/03/01 Ed:3.0	Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
IEC 60601-2-50 Issue:2000/07/01 Ed:1	Medical Electrical Equipment - Part 2-50: Particular Requirements for the Safety of Infant Phototherapy Equipment Includes TRFs for UV/IR Testing and Sound Testing to IEC 60601-2-50 2nd edition issue 3/9/2009

In addition to the above 3rd party certifications, Lumitex has performed substantial verification and equivalence bench testing for the Giraffe Blue Spot PT Lite and the predicate device described earlier. The tests are included with this submission and include phototherapy

comparative spectral irradiance levels with temperature and humidity levels at the maximum device environmental ratings as well as nominal room environments.

The results of the bench testing show that the Giraffe Blue Spot PT Lite provides equivalent therapeutic overhead phototherapy treatment as the predicate Giraffe Spot PT Lite by Ohmeda Medical. Both devices were tested in their minimum and maximum environmental conditions. Both devices are comprised of a box containing a light source and both utilize a flexible light pipe to position and direct the light onto a patient from above.

The major difference between the two Giraffe designs is that the Giraffe Blue Spot PT Lite utilizes a narrow bandwidth LED that emits light in the desired "blue" spectrum versus the use of a broad spectrum "white" light metal-halide bulb in the predicate Giraffe Spot PT Lite. LED light sources can be found in similar FDA approved devices such as the Bilisoft Phototherapy System (K053568).

Another notable difference is that the Giraffe Blue Spot PT Lite does not require a quartz rod to buffer the optical transmission fiber from the heat developed by the light source as is the case in the predicate Giraffe Spot PT Lite.

Based on the direct comparative testing with predicate devices and the extensive 3rd party testing to international standards, the Giraffe Blue Spot PT Lite is believed to be safe and effective for the treatment of hyperbilirubinemia.

Sterilization Information

The Giraffe Blue Spot PT Lite is not intended to be supplied sterile. Cleaning and disinfecting instructions can be found in the Operation, Maintenance, and Service Manual.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. David Felty, P.E.
Director of Engineering
Lumitex, Incorporated
8443 Dow Circle
Strongsville, Ohio 44136

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Re: K120820
Trade/Device Name: Giraffe Blue Spot PT Lite
Regulation Number: 21 CFR 880.5700
Regulation Name: Neonatal Phototherapy Unit
Regulatory Class: II
Product Code: LBI
Dated: May 15, 2012
Received: May 17, 2012

Dear Mr. Felty:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Giraffe Blue Spot PT Lite

Indications For Use:

The Giraffe Blue Spot PT Lite phototherapy system provides light therapy for the treatment of hyperbilirubinemia, commonly known as neonatal jaundice, during the newborn period in the hospital.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH. Office of Device Evaluation (ODE)

6/6/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
nfection Control, Dental Devices

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